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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,149	12/21/2001	Michael Leslie Kotewicz	0942.049000A/RWE/MITT	4033

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STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/024,149

Applicant(s)

KOTIEWICZ ET AL.

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-23 are cancelled by amendment and claims 24-75 are added and are pending in this application.
2. The Information Disclosure Statement filed on March 5, 2003 has been entered.
3. This application is a continuation of US nonprovisional 09/220,330 filed on December 24, 1998, which claims priority to US nonprovisional 07/143,396, filed on January 13, 1988.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

A. Claims 24-75 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-83, 91-93 of U.S. Patent No.6,610,522 ('552). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1-42 of the patent ('552) are drawn to a composition comprising

(a) an mRNA template

(b) an reverse transcriptase (M-MLV) having DNA polymerase activity, wherein said reverse transcriptase allows the mRNA template to remain intact during one minute cDNA synthesis reaction by said reverse transcriptase as determined by gel electrophoresis and wherein

said reverse transcriptase is modified within the RNase domain. Claims 91-93 of the patent ('552) further recite the process for preparing the cDNA molecule. The obvious variation between the instant claims and the patented claims is the claim language referring to product made by the process. Therefore, the instant claims are obvious over '552.

B. Claims 24-25, 32-33, 40-41, 48-49, 56-57 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No.5,668,005 ('005). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-20 of the patent ('005) are drawn to a composition comprising

An isolated DNA molecule comprising a nucleotide sequence encoding a polypeptide having DNA polymerase activity and substantially no RNaseH activity, wherein said nucleotide sequence is derived from Moloney murine leukemia virus (M-MLV) nucleotide sequence, and method for preparing a cDNA molecule using the said DNA molecule. The obvious variation between the instant claims and the patented claims is the claim language referring to product made by the process. Therefore, the instant claims are obvious over '005.

C. Claims 24-25, 28-33, 36-41, 44-49, 52-55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 116-125, 189, 192-194 of U.S. Patent No.6,063,608 ('608). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 116-125 of the patent ('608) are drawn to a composition comprising a reverse transcriptase having DNA polymerase activity and reduced RNase H activity, wherein reverse transcriptase allows preparation of cDNA without

significant degradation of an mRNA template as determined by gel electrophoresis, and claims 189, 192-194 disclose a method for preparing a cDNA molecule using said reverse transcriptase.

The obvious variation between the instant claims and the patented claims is the claim language referring to product made by the process. Therefore, the instant claims are obvious over ‘608.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The rejections are based on MPEP 2113, which notes-

“[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process

claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

A. Claims 24-75 are rejected under 35 U.S.C. 102(e) as being anticipated by Goff et al. (USPN. 4,943,531).

Goff et al. teach a composition of claims 24-75, comprising cDNA (see column 24, lines 43-67, column 25, lines 1-59).

With regard to claims 24-75, Goff et al. also teach that (i) the average size of cDNA product was 1200 bases, which represents approximately about 100% full length cDNA (see column 26, lines 39-67, which meets the limitation of 34% full length); (ii) the retroviral reverse transcriptase is M-MLV reverse transcriptase (see column 24, lines 43-67, column 3, lines 9-40, which inherently has DNA polymerase activity); (iii) M-MLV reverse transcriptase comprises 728 amino acids (see column 3, lines 9-40, which meets the limitations in the instant claims 26-28, 34-35, 42-43, 50-51, 58-59); (iv) cDNA synthesis is monitored by gel electrophoresis (see column 25, lines 2-37, column 26, lines 2-67). Thus the disclosure of Goff et al. meets the limitations in the instant claims.

B. Claims 24-75 are rejected under 35 U.S.C. 102(b) as being anticipated by Boone et al. (Proc.Natl.Acad.Sci.USA).

Boone et al. teach a composition of claims 24-75, comprising cDNA (see page 847, column 2, paragraph 4). Boone et al. also teach that the use of retrovirus reverse transcriptase in cDNA synthesis (see page 847, column 2, paragraph 4); the average size of cDNA was correspondent to the actual size of the template (7.7kb and 8.0kb) that is 100% full length cDNA

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product was made (see page 849, column 1, paragraph 1, Fig.2, column 2, paragraph 2); (iii) analysis of cDNA product by gel electrophoresis (see page 849, Fig.2). Thus the disclosure of Boone et al. meet the limitations in the instant claims.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

^{epc}
Suryaprabha Chunduru
May 26, 2004

Jehanne Sitton
JEHANNE SITTON
PRIMARY EXAMINER
5/27/04